

Advisory Committee on Toxic Substances Paper		ACTS/21/2004	
Meeting date:	8 July 2004	Open Govt. Status:	Fully Open
Type of paper:	Special Category	Paper File Ref:	HD/354/1007/03
Exemptions:	None		

ADVISORY COMMITTEE ON TOXIC SUBSTANCES

SUBTILISINS

A Paper by Richard Pedersen

Cleared by Michael Topping on 11 June 2004

Issue

1. Establishment of an occupational exposure limit for subtilisins. Report back from the consultation exercise.

Timing

2. Routine. The limit will not come into force until after the new framework for occupational exposure limits is established in late 2004.

Recommendation

3. That ACTS agrees that the Health and Safety Commission be asked to agree the following Maximum Exposure Limit (MEL):

Subtilisins 0.00004 mg.m⁻³ (40 ng.m⁻³) (8-hour TWA)

This limit is likely to be published as a Workplace Exposure Limit, subject to the agreement of ACTS and the HSC to the new occupational exposure limit framework.

Background

4. In March 2003 ACTS agreed that consultation should go ahead on the establishment of a maximum exposure limit (MEL) for subtilisins (ACTS/08/2003). It was agreed that this consultation should ask consultees' opinion on a MEL of 40 ng.m⁻³ (8-hour TWA) and a short-term (15 minute) MEL at the same value.
5. A Consultative Document containing these proposals, and an additional proposal for a MEL for Refractory Ceramic Fibres, was published on 2 June 2003 (CD 187) with a consultation period lasting until 1 September 2003. A list of bodies and individuals consulted directly is attached at Annex 1. The Consultative Document was also placed on the HSE's website.

6. At the ACTS meeting held on 25 March 2004, members received a report on the results of this consultation as regards RCFs, and agreed a recommendation to the Health and Safety Commission. HSE was not then in a position to report back fully on responses to the proposed limits for subtilisins. The delay over a final position on subtilisins was caused by the need to carry out further sampling of subtilisin exposure, and to consult further with the industry most affected by the proposed new limit.

Argument

7. 25 comments were received altogether on the Consultative Document, of which 5 were "no comment". Of the 20 substantive comments, 8 dealt solely with subtilisins and 7 dealt with both substances (5 dealt solely with RCFs). A list of those commenting on subtilisins is attached at Annex 2.
8. Of the 15 organisations/individuals who commented on the subtilisins proposal, 8 expressed full support with HSC's proposals. One further response made no actual comment on the proposals put forward. Two further responses were received from occupational hygiene consultants. While these organisations made useful suggestions concerning the control of subtilisins in the workplace, they did not comment on the proposed MEL. HSE has written to both consultant organisations in response to the direct questions that they raised.
9. The remaining four responses received came from the detergent industry, which is the main user of subtilisins, and from a related company that supplies the industry with the subtilisins enzyme. They questioned the data on which HSC's proposals were based, and have since been sent all the related WATCH and ACTS papers going back to 2000.
10. Officials from HSE and the Health and Safety Laboratory held a productive meeting with industry representatives in April 2004. Although the detergent industry continued to have certain reservations about the proposed limit, these did not relate to compliance. Consequently, HSE decided that it was fully justified in progressing its proposals for a MEL set at 40 ng.m^{-3} (8-hour TWA).
11. At the time of going to public consultation, there was some question as to whether it was appropriate to have a short-term exposure limit for subtilisins, and whether this too should be set at 40 ng.m^{-3} . The Consultation Document specifically asked consultees whether a short-term limit was measurable. Consultees who made reference to the issue (4) suggested that it was not possible to measure such a small quantity of enzyme in a sufficiently accurate way. Additionally, the Health and Safety Laboratory had concerns over setting a STEL at 40 ng.m^{-3} . In order for HSE to propose such a short-term limit, it would be necessary to have a lower detection limit, in the region of 0.2 ng/ml. Detection limits currently used in the measurement assay are in the region of 1-2 ng/ml. HSE therefore believes that it is not appropriate to recommend a short-term exposure limit to ACTS.

Link to HSC Strategy

12. Subtilisins are respiratory sensitisers and are therefore a priority substance for consideration under HSE's Chemicals Programme, established under the Health and Safety Hazards Strategic Programme.

Communication Plan

13. The new limit will be fully publicised as part of the information provided on the new Occupational Exposure Limit framework. HSE expects that this framework will be fully in place in late-2004, at which time the new limit for subtilisins will come into force.

Evaluation Plan

14. HSE intends to evaluate the effectiveness of the new limit within two years of its coming into force. Monitoring visits to principal users are planned.

Relevant Control Systems

15. In the soap detergent industry there is already a high degree of automation, containment, engineering controls and the use of PPE, in order to control residual risks. In other industries where subtilisins are used – preparation of animal feeds, food processing and leather processing – much of the product will be in pelletised form leading to a much lower level of dustiness.

Consultation

16. See paragraph 5, paragraphs 7 to 9 and Annexes 1 and 2.

Costs and Benefits

17. These were fully considered in the Regulatory Impact Assessment conducted prior to consultation, and attached to ACTS paper ACTS/08/2003.

Action

18. ACTS is requested to agree that a paper be submitted to the Health and Safety Commission seeking its agreement to the establishment of the following Maximum/Workplace Exposure Limit:

Subtilisins	0.00004 mg.m ⁻³ (40 ng.m ⁻³) (8-hour TWA)
-------------	--

Contact

ACTS Secretariat

Tel: 020 7717 6184

Fax: 020 7717 6190

ORGANISATIONS AND INDIVIDUALS CONSULTED

Government Departments

Cabinet Office – European Secretariat
Cabinet Office – Office of Public Service
Cabinet Office – Regulatory Impact Unit
Central Office of Information
Crown Estate Commissioners
Department for Education and Skills
Department for Environment, Food and Rural Affairs
 Agricultural Resources Policy Division
 Central Directorate on Environmental Protection
 Chemicals and Biotechnology Division
 Global Atmosphere Division
 Waste Policy Division
Department of Agriculture and Rural Development – Northern Ireland
Department of Health
Department of Trade and Industry
Department of Trade and Industry – Small Firms Policy Branch
Department of Transport
Department of Work and Pensions – HSSD
Foreign and Commonwealth Office
Health and Safety Agency for Northern Ireland
HM Customs and Excise
HM Prison Service
HM Treasury
Home Office
Law Officer's Department
Lord Chancellor's Department
Ministry of Defence
National Assembly for Wales
Northern Ireland Department of Economic Development
Northern Ireland Office
Office of the Deputy Prime Minister
Property Advisers to the Civil Estate
Scottish Executive

Public Bodies

Agricultural Training Board
British Broadcasting Corporation
Central Offices of Industrial Tribunals
Civil Aviation Authority
Countryside Commission
Environment Agency
Environment Council

Forestry Commission
Historic Royal Palaces Agency
House of Commons Library
House of Lords Library
Joint Nature Conservation Committee
Laboratory of the Government Chemist
Law Commission
Maritime and Coastguard Agency
National Consumer Council
Office for National Statistics
Rural Development Commission
Scottish Law Commission

European Union, Crown Dependencies and Overseas Territories

Government of Gibraltar
Health and Safety Authority – Republic of Ireland
Health and Safety Inspectorate, Guernsey
Isle of Man Local Government Board
Social Security Department, Jersey
UK Permanent Representation to the European Union

Local Government Organisations

Association of Local Authorities of Northern Ireland
Association of London Authorities
Convention of Scottish Local Authorities
Local Government Association
London Boroughs Association
National Association of Local Councils

Employers' Organisations and Small Firms' Representatives

Alliance of Independent Retailers
Association of British Chambers of Commerce
Association of Independent Businesses
British Pottery Managers Association
Building Employers Federation
Confederation of British Industry
CBI – Smaller Firms Council
Engineering Employers' Federation
Federation of Small Businesses
Institute of Directors
National Federation of Self Employed and Small Businesses
Union of Independent Companies
Universities and Colleges Employers' Federation

Trade Unions and Employee Organisations

Amalgamated Union of Engineering Workers

Amicus
Association of Teachers and Lecturers
Bakers Food and Allied Workers Union
BECTU
BIFU
British Medical Association
Communications Workers Union
Confederation of Shipbuilding and Engineering Unions
Fire Brigades Union
General Federation of Trade Unions
GMB
Graphical Paper and Media Union
National Association of Colliery Overmen, Deputies and Shotfirers
National Association of Fire Officers
NUMAST
Police Federation of England and Wales
Prospect
Royal College of Nursing
Scottish Police Federation
Scottish Trades Union Congress
Society of Radiographers
Trades Union Congress
Transport and General Workers Union
UCATT
UNISON
USDAW

Trade Associations and Learned Bodies

Abrasive Industries Association
Adhesive Tape Manufacturers Association
Agricultural Engineers Association
Association of Bakery Ingredient Manufacturers
Association of British Launderers and Cleaners
Association of British Mining Equipment
Association of British Pharmaceutical Industry
Association of Light Metal Founders
Association of Manufacturers of Fermentation Enzyme Products
Bakery Allied Traders Association
BCL Leather Technology Centre
Brick Development Association
British Adhesive and Sealants Association
British Aerosol Manufacturers Association
British Aggregate Construction Materials Industries
British Agricultural and Garden Machinery Association
British Agrochemicals Association
British Apparel and Textile Confederation
British Association of Chemical Specialities
British Association of Feed Supplement Manufacturers
British Cable Makers Confederation

British Cast Iron Research Association
British Ceramic Confederation
British Chemical Distributors and Traders Association
British Chrome and Chemicals
British Coatings Federation
British Colour Makers Association
British Floor Covering Manufacturers Association
British Foundry Association
British Headwear Industries Association
British Iron Founders Association
British Lubricants Association
British Metal Castings Council
British Metal Finishing Suppliers Association
British Metallurgical Plant Constructors
British Non-Ferrous Metals Federation
British Pest Control Association
British Polymer Training Association
British Rigid Urethane Foam Manufacturers
British Rubber Manufacturers Association
British Secondary Metals Association
British Textile Technology Group
British Veterinary Association
British Wood Preservation and Damp Proofing Association
Castings Development Centre
Chemical Industries Association
Company Chemists Association
Confederation of British Wool Textiles
Cosmetics, Toiletries and Perfumeries Association
Dairy Industry Federation Ltd
Electric Battery Manufacturers Association
European Ceramic Fibres Industry Association
Farmers Union of Wales
Federation of Civil Engineering Contractors
Fertiliser Manufacturers Association
Food and Drink Federation
Foundry Trade Equipment and Supplies Association
Freight Transport Association
Grain and Feed Trade Association
Independent Tank Storage Association
Law Society of England and Wales
Law Society of Scotland
National Farmers Union of Scotland
National Federation of Demolition Contractors
National Specialist Contractors' Council
Offshore Contractors Association
Paint Research Association
Retail Motor Industry Federation
Road Haulage Association
Royal Agricultural Society of England
Royal Highland and Agricultural Society of Scotland

Royal Pharmaceutical Society of Great Britain
The Royal Society
Royal Society of Chemistry
Scotch Whisky Association
Scottish Pharmaceutical Federation
Scottish Seed and Nursery Trade Association
Scottish Steel Founders Association
Seed Crushers and Oil Processors Association
Shoe and Allied Trades Research Association
Silica and Moulding Sands Association
Soap and Detergent Industry Association
Society of British Aerospace Companies
Society of British Gas Industries
Society of Chemical Industry
Society of Dyers and Colourists
Solvents Industry Association
Steel Castings Research and Trade Association
Surface Engineering Association
Textile Services Association
Timber Trade Association
Timber Packaging and Pallet Confederation
UK Cleaning Products Industry Association
United Kingdom Agricultural Supply Trade Association
Water Companies Association
Water Services Association of England and Wales
Welding Manufacturers Association

Police and Emergency Services Bodies

Association of Chief Police Officers of England, Wales and Northern Ireland
Association of Chief Police Officers of Scotland
Association of Scottish Police Superintendents
Chief and Assistant Chief Fire Officer' Association

Health and Safety Specialists

Association of Port Health Authorities
Biotechnology and Biological Sciences Research Council
British Industrial Biology Research Association
British Institute of Occupational Hygiene
British Occupational Hygiene Society
British Safety Council
Chartered Institute of Environmental Health Officers
Council of Independent Inspecting Authorities
Institute of Occupational Hygienists
Institute of Occupational Medicine
Institution of Occupational Safety and Health
Natural Environment Research Council
Newcastle Occupational Health
Royal Environmental Health Institute of Scotland

Royal Society for the Prevention of Accidents
Society/Faculty of Occupational Medicine

Individual Companies

Acorus Therapeutics Ltd
Albright and Wilson
Aon Ltd
Aplin and Barrett Ltd
Arkady Craigmillar Ltd
British Bakels Ltd
Broadland Foods Ltd
Carbolite
Cereform Ltd
City Technology Ltd
Damsco (UK) Ltd
Finnfeeds International Ltd
Fisons plc
Genencar International
Genesis Environmental Ltd
Huntsman Surface Sciences
ICI Chemicals and Polymers
Innology
Lever Brothers Ltd
Lever Products UK Ltd
Lloyds (Animal) Feeds Ltd
London Underground
Novo Nordisk Bioindustries UK Ltd
Premier Poultry Ltd
Procter and Gamble Ltd
Robert McBride Ltd
St Gobain Industrial Ceramics
Thermal Ceramics
Unilever
Unilever Research

Academic Institutions

Imperial Cancer Research Fund
Institute of Cancer Research
University of Birmingham – Institute of Occupational Health
University of Dundee – Wolfson Institute of Occupational Health
University of Manchester – Department of Occupational Health
University of Newcastle-upon-Tyne – Department of Occupational Health

Other Organisations

The Consumers Association

**ORGANISATIONS COMMENTING ON THE SUBTILISINS PROPOSAL IN
CONSULTATIVE DOCUMENT CD187**

- 1 City Technology Ltd
- 2 Mr S Ellis
- 3 Genesis Environmental Ltd
- 4 Industrial Health Control Ltd
- 5 London Underground Ltd
- 6 Novozymes A/S
- 7 Robert McBride Ltd
- 8 Roche Vitamins UK Ltd
- 9 Society/ Faculty of Occupational Medicine
- 10 Terra Nitrogen (UK) Ltd
- 11 TGWU – Plymouth
- 12 Trades Union Congress
- 13 Transport and General Workers Union
- 14 Unilever Colworth Laboratory
- 15 United Kingdom Cleaning Products Industry Association